

PAUL H. FACKLER, PH.D.

1090 Horsham Road
North Wales, PA 19454-1505

PROFESSIONAL EXPERIENCE:

TEVA PHARMACEUTICALS

NORTH WALES, PA

Senior Director, Product and Biopharmaceutics Strategy Development (Jan. 2003 – Present)
Senior Director, Biopharmaceutics and Preformulation (Apr. 2002 – Dec. 2002)
Director, Biopharmaceutics (Jun. 2000 – Mar. 2002)

Continued with Teva after their acquisition of Copley. Currently in the group managing international issues related to the placement of R&D programs into and bioequivalence studies originating from R&D sites in Hungary, the Netherlands, Israel, Canada, Mexico, and the United States. Responsible for the coordination of multi-national bioequivalence testing and registration of generic products. Works with outside business development interests and new technologies for Teva Pharmaceuticals. Provides new market opportunity analyses and assessments.

COPLEY PHARMACEUTICAL, INC.

CANTON, MA

Director, Clinical and R&D Compliance (Oct. 1998 – May 2000)

Directed compliance activities within the Research and Development department. Responsibilities included managing the group reviewing and approving analytical data supporting ANDAs, SOP initiation, revision, and training, ensuring GMP maintenance and calibration of instrumentation, and compilation of training records for R&D personnel. Managed stability program for R&D, ANDA submission, and bioequivalence (BE) study batches. Contracted, monitored, and evaluated bioequivalence studies for oral, mucosal, and topical generic products as well as initial design of clinical programs for NDA submissions. Designed and reviewed BE study protocols for compliance with FDA guidance documents and regulations. Evaluated bioanalytical methods and validations for BE studies, reviewed/edited BE study reports, and monitored/inspected BE studies at clinics.

CAMBRIDGE SCIENTIFIC, INC.

BOSTON, MA

Director, Biomaterials R&D (Aug. 1997 – Sep. 1998)

Reported to the president of this start-up company. Directed several projects on the use of bioresorbable polymers for medical applications. These included controlled release delivery systems, vaccine delivery, bone fixation devices, spinal fusion devices, and polymers with non-linear optical properties. Responsible for regulatory affairs and cGMP/GLP issues with both in-house and subcontracted research and production.

SPRINGBORN LABORATORIES, INC.

WAREHAM, MA

Research Director, Pharmaceutical and Environmental Chemistry (Jan. 1996 – Jul. 1997)
Manager, Metabolism and Analytical Chemistry (Apr. 1989 – Dec. 1995)
Manager, Chemistry Department (Jan. 1987 – Mar. 1989)

Reported to the company president of this multi-disciplinary CRO. The principal consultant for FDA registration programs, specifically QA, CMC, and EA issues for IND, NDA, ANDA, NADA, and 510k submissions. Provided regulatory consulting, CMC, and EA preparation to pharmaceutical clients as well as FIFRA applications for pesticides. Was responsible for chemistry and microbiology laboratory cGMP/GLP studies (more than 800 per year conducted), technical reporting, and Quality Assurance of the same. Provided technical supervision for all aspects of the analytical laboratory and for advising research groups working on preclinical chemistry, metabolism, microbiology, genetic toxicology, and environmental chemistry supporting pharmaceuticals, specialty chemicals, and agrochemicals. Expanded program activities and hired personnel building the department to 75 people (10 Ph.D.s) from an initial department of eight. Assisted in the establishment of the European based sister-laboratory (Switzerland).

JOHNSON MATTHEY, INC.

WEST CHESTER, PA

Group Leader, Analytical Chemistry (Jan. 1986 – Dec. 1986)
Senior Research Chemist (Mar. 1985 – Dec. 1985)

Directed analytical chemistry group for projects involving development of second and third generation platinum-containing anti-cancer drugs, gold based cancer and arthritis therapies. Instrumental in the development of a new pre-clinical testing service. Worked closely with major pharmaceutical companies on cooperative research programs. Responsibilities included supervision of personnel, compilation of annual reports and program summaries, presentations to outside collaborators and sponsors, and maintenance of analytical instrumentation (HPLC, GC, ICP, AA, NMR, C,H,N analyzer).

UNIVERSITY OF CINCINNATI

CINCINNATI, OH

Postdoctoral Assistant (Jan. 1984 – Feb. 1985)
Worked on projects that dealt primarily with identification of nanogram quantities of technetium-based radiopharmaceuticals. Instrumental techniques included HPLC, whole-body gamma imaging, liquid scintillation counting, TLC, NMR, and mass spectrometry.

EDUCATION:

Ph.D. Analytical/Inorganic Chemistry, Boston College, Chestnut Hill, MA, 1984
B.S. Chemistry, Harvey Mudd College, Claremont, CA, 1978

PROFESSIONAL AFFILIATIONS:

American Association of Pharmaceutical Scientists
American Chemical Society
Drug Information Association
Generic Pharmaceutical Association
Parenteral Drug Association
Product Quality Research Institute - Biopharmaceutics Technical Committee chair
United States Pharmacopeia - Biopharmaceutics Committee – Project Team #6 member

PUBLICATIONS:

- Smith, D.J., Trantolo, D.J., King, W.F., Gusek, E.J., Fackler, P.H., Gresser, J.D., DeSouza, V.L., Wise, D.L., 2000. Induction of Secretory Immunity with Bioadhesive Poly(d,l-lactide-co-glycolide) Microparticles Containing *Streptococcus Sobrinus* Glucosyltransferase, Oral Microbiology and Immunology, 15(2), 124.
- Kent, D., Fackler, P., Hartley, D., Hobson, J., 1996. Interpretation of Data from Nonstandard Studies: The Fate of Octamethylcyclotetrasiloxane in a Sediment/Water Microcosm System, Environmental Toxicology and Water Quality, 11, 145.
- Fackler, P.H., Dionne, E., Hartley, D.A., Hamelink, J.L. 1995. Bioconcentration by Fish of a Highly Volatile Silicone Compound in a Totally Enclosed Aquatic Exposure System, Environmental Toxicology and Chemistry, 14(10), 1649.
- Mao, J., Dennis, M.W., Foster, R., Fackler, P.H. 1994. Analysis of Diethylenetriamine in Water and Soil at ppb Levels by High Performance Liquid Chromatography with Fluorescence Detection, Journal of Liquid Chromatography, 17(11), 2485.
- Mao, J., Erstfeld, K.M., Fackler, P.H. 1993. Simultaneous Determination of Tralomethrin, Deltamethrin and Related Compounds by HPLC with Radiometric Detection, Journal of Agricultural and Food Chemistry, 41(4): 596.
- Clarke, M.J., Kastner, M.E., Podbielski, L.A., Fackler, P.H., Schreifels, J., Meinken, G., Srivastava, S.C. 1988. Low-symmetry, Mixed-Valent, μ -Oxo Technetium Complexes with Pyridine and Halide Ligands, Journal of the American Chemical Society, 110(6): 1818
- Clarke, M.J., Podbielski, L.A., Kastner, M.E., Fackler, P.H. 1987. Oxo Technetium Complexes with Pyridine and Halide Ligands, in Technetium in Chemistry and Nuclear Medicine, Raven Press, 29
- Abrams, M.J., Fackler, P.H., Picker, D.H., Lock, C.J.L., Howard-Lock, H.E., Faggiani, R., Teicher, B.A., Richmond, R.C. 1986. The Synthesis and Structure of [Rhodamine 123]₂PtCl₄H₂O. The First Tetrachloroplatinate(II) Salt with Anti-cancer Activity, Inorganic Chemistry, 25(22): 3980
- Kastner, M.E., Fackler, P.H., Podbielski, L., Charkoudian, J., Clarke, M.J. 1986. A Dissymmetric μ -Oxo Technetium Complex, Inorganica Chimica Acta, 114(1): L11

Lindsay, M.J., Fackler, P.H., Clarke, M.J., Kastner, M.E. 1985. Synthesis and Structure of *trans*-[O₂(Im)₄Tc]Cl₂H₂O, *trans*-[O₂(1-Me-Im)₄Tc]Cl₃H₂O and Related Compounds, Inorganica Chimica Acta, 109(1): 39

Fackler, P.H., Kastner, M.E., Clarke, M.J., Deutsch, E. 1984. Synthesis and Structure of *trans*-[O₂(TBP)₄Tc]⁺ (TBP = 4-*tert*-butylpyridine) and Related Complexes. Inorganic Chemistry, 23(26): 4683

Fackler, P.H., Kastner, M.E., Clarke, M.J. 1984. Synthesis, Spectra, and Structure of *af*-dibromo-*b*-ethoxy-*d*-oxo-*ce*-bis(4-nitropyridine)technetium(V) and Related Complexes, Inorganic Chemistry, 23(24): 3968

Fackler, P.H. 1984. Ph.D. Thesis. Technetium Complexes of Pyridines and Imidazoles, Boston College

Clarke, M.J., Fackler, P.H. 1982. The Chemistry of Technetium: Toward Improved Diagnostic Agents. Structure and Bonding, 50: 55

PRESENTATIONS:

Fackler, P.H., 2004. Bioequivalence for Biogenerics: Strategies in Addressing Common Myths and Misconceptions. Presented at the Marcus Evans 2nd Annual Generic Drugs Forum. Philadelphia, PA. January 2004.

Fackler, P.H., 2001. Applying the Biopharmaceutical Classification System (BCS). Presented at the Barnett International Conference on Bioavailability and Bioequivalence. Washington, DC. February 2001.

Fackler, P.H., 2000. Identifying Outliers in Bioanalytical Methods Validation: Maintaining Balance between Common Sense and Statistics. Presented at the Institute for International Research Conference on Bioanalytical Methods Validation. Princeton, NJ. December 2000.

Fackler, P.H., 2000. Case Study #4. Presented at the AAPS/FDA Symposium - Biopharmaceutics Classification System: FDA Guidance and Implementation. Arlington, VA. September 2000.

Gresser, J.D., Trantolo, D.J., Fackler, P.H., White, R.L., Wise, D.L., 1998. Molecularly Reinforced Biodegradable Internal Fixation Devices. Presented at the Materials Research Society National Meeting. Boston, MA. November 1998.

Trantolo, D.J., White, R.L., Gresser, J.D., Fackler, P.H., Wise, D.L., Bondre, S., Bryan, D.J., 1998. Resorbable Structures for Schwann Cell Enhanced Peripheral Nerve Regeneration. Presented at the Materials Research Society National Meeting. Boston, MA. November 1998.

Gresser, J.D., Trantolo, D.J., White, R.L., Fackler, P.H., Wise, D.L., Lewandrowski, K., 1998. Development of Resorbable Bone Cement. Presented at the Materials Research Society National Meeting. Boston, MA. November 1998.

Trantolo, D.J., White, R.L., Gresser, J.D., Fackler, P.H., Wise, D.L., Frazier, D.O., 1998. Microgravity Processing of Biopolymer/Metal Composites for Non-linear Optical Applications. Presented at the Materials Research Society National Meeting. Boston, MA. November 1998.

Fackler, P.H., 1998. Validation Requirements for Equipment in Pharmaceutical Analytical Laboratories. Presented at the Barnett International Conference on Stability Testing and Analytical Procedure Validation. Princeton, NJ. September 1998.

McCabe, D.M., Armitage, A.E., Aubut, L.K., Fackler, P.H., 1998. Fumigation-Extraction: A Comparison of Techniques. Presented at the 215th National Meeting of the American Chemical Society. Dallas, TX. March 1998.

Fackler, P.H., 1997. Industry Approaches to Environmental Assessments. Presented at the 33rd Annual Meeting of the Drug Information Association, Montreal, Canada. June 1997.

Fackler, P.H. 1996. Technical and Regulatory Aspects of Agrochemical Environmental Fate and Metabolism Studies in the United States and Europe. Presented at the Society of Agricultural Chemical Industry. Tokyo, Japan. May 1996.

Fackler, P.H. 1996. Environmental Assessments in the United States (following the November 1995 FDA Guidance for Industry). Presented at the 8th Annual Eurometing of the Drug Information Association. Copenhagen, Denmark. May 1996.

Fackler, P.H. 1995. Biodegradation of Pharmaceuticals. Presented at the 31st Annual Meeting of the Drug Information Association, Orlando, FL. June 1995.

Mao, J., Watson, C.F., Dix, M.E., Fackler, P.H. 1994. pH Dependent Hydrolysis of 2-Hydroxypropylmethanethiolsulfonate. Presented at the 207th National Meeting of the American Chemical Society. San Diego, CA. March 1994.

Fackler, P.H., Erstfeld, K.M., O'Grodnick, J.S., Mao, J. 1992. Tralomethrin and Deltamethrin - Fate during an Aquatic Microcosm Study. Presented at the 13th Annual Meeting of the Society of Environmental Toxicology and Chemistry, November 1992, Paper #294.

Fackler, P.H., Dionne, E., Hamelink, J., Hobson, J. 1992. Bioconcentration of Octamethylcyclotetrasiloxane (OMCTS) in Fathead Minnows. Presented at the 13th Annual Meeting of the Society of Environmental Toxicology and Chemistry, November 1992, Paper #277.

Fackler, P.H., Dionne, E., Hartley, D.A. 1992. Bioconcentration Studies: A Comparison of the One Compartment Model to Actual Exposure Data Collected. Presented at the 204th National Meeting of the American Chemical Society. Washington, DC. August 1992.

Mao, J., Fackler, P.H. 1992. Use of HPLC with Flow-through Radiometric Detection for Low-level Environmental Analysis. Presented at the 204th National Meeting of the American Chemical Society. Washington, DC. August 1992. Analytical Paper #15.

Fackler, P.H. 1991. Environmental Fate Studies Targeted for FDA Submission. Presented at the 7th Annual Meeting of the Society for Quality Assurance. Kansas City, MO. October 1991. Session C - Environmental Fate.

Hartley, D.A., Fackler, P.H. 1990. Biodegradation Testing - An Overview. Presented at the Annual Meeting of the American Nuclear Society. Nashville, TN. June 1990. Biology and Medicine Division. Section 1.2.

Fackler, P.H., Czerwinska, A., Deutsch, E., Yelton, R., Schumaker, R. Lieberman, M.L. 1985. Synthesis, Characterization, and Thermal Decomposition of $t[Co(^{15}NH_3)(N_4CCN)(NH_3)_4](ClO_4)_2$. Presented at the 190th National Meeting of the American Chemical Society; Chicago, IL; September 1985; Inorganic Paper #175

Fackler, P.H., Kastner, M.E., Clarke, M.J. 1982. Synthesis and Structure of Oxo Technetium Complexes with Pyridine Ligands. Presented at the 186th Meeting of the American Chemical Society; Washington, DC; August 1983; Inorganic Paper #106

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